

REMARKS

Applicant has received and carefully reviewed the Final Office Action of June 12, 2008.

Applicant has amended claims 8, 11-15, 18, 20-21, 24, and 27-29, and cancelled claims 1-7, 9, 23 and 26, in order to further refine and clarify that which the Applicant regards as the claimed invention. Support for the amendments can be found throughout the specification, and in particular, on pages 8 and 12. No new matter has been added by these amendments.

Rejection under 35 U.S.C. §102(b)

The Examiner rejected claims 27-29, under 35 U.S.C. §102(b), as anticipated by Nilsson (WO 91/00074). According to the Examiner, Nilsson teaches a kit comprising a device for urinary catheterization and a pharmaceutically active composition comprising a hormone for insertion into a female urethra. Applicant respectfully traverses this rejection.

In the present Office Action, the Examiner argues that Applicant's description of the indwelling catheter of Nilsson as adapted for long-term use, is merely reciting an intended use and

not a structural difference. Applicant strongly disagrees.

The catheter of Nilsson is specifically designed to fit into the urethra, and to be inserted in the urethra with retaining members or collars that are located between the musculature surrounding the urethra. The conical end or collar 14 of said catheter, abuts against the wall of the urethra to seal it. Another collar 16 is located distally and is angled in the opposite direction from collar 14, so as to stay in the desired position (Nilsson at pages 8-10) even with normal movement of the user.

Applicant submits that it is well known in the catheter and urological arts, that indwelling catheters are designed to stay in place by the use of retaining members so that users can move about. See for example, U.S. Patent No. 7,264,609 and the prior art discussion within. In contrast, intermittent catheters, such as those disclosed by Applicant, do not possess collars, or balloons, or other features designed to hold the catheter in the urethra. The user holds the catheter in place when needing to void the bladder, and then the catheter is removed up to six times a day. Intermittent catheters such as Applicant's, do not comprise retaining members that internally hold the catheter within the

urethra. See, for example, intermittent catheters described in U.S. Patent Nos. 6,059,107 and 6,355,005. In addition, Applicant has provided herewith two articles retrieved from a search of the internet, which clearly show that one of ordinary skill in the catheter arts would understand the differences in structure between indwelling catheters and intermittent catheters (Appendix A).

For the Examiner to argue that the indwelling catheter of Nilsson can be used as an intermittent catheter goes against the teachings in the art. The term "intermittent" is not an intended use, but a description of a type of catheter with a structure known to those of ordinary skill in the art. As such, Nilsson does not teach the catheter of Applicant's claimed invention.

Moreover, in view of Applicant's amended claims, Nilsson also does not teach or suggest a catheter having a hydrophilic polymer coating, and at least a portion of the polymer coating being impregnated with a pharmaceutically active composition. Further, Nilsson does not teach that the pharmaceutically active composition is at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, and said pharmaceutically active

composition is coated with a water soluble coating. The composition is provided on the outer proximal surface of the catheter so that delivery of the composition to the urethra is direct, and complete in a relatively short time (e.g. minutes).

Instead, Nilsson allegedly teaches that the hollow conical part 14 may accommodate a viscous fluid such as a hormone preparation (page 8, lines 3-6), and teaches that the contents of the conical portion are dispensed only when the user moves from a sitting to a standing position, or other normal movements e.g. squeezes the catheter (Nilsson at page 10).

In view of the foregoing remarks, and in view of Applicant's amended claims, Applicant submits that Nilsson does not teach each and every element of Applicant's claimed invention, and therefore cannot anticipate claims 27-29 as amended. Applicant respectfully requests withdrawal of this rejection.

Rejection under 35 U.S.C. §103(a)

The Examiner maintained the rejection of claims 1-4, 6-14, and 21-26 as unpatentable over Nilsson, in view of WO 02/24246 to Hunter. Nilsson is offered by the Examiner for teaching a

catheter comprising a pharmaceutical composition. The Examiner admits, however, that Nilsson does not teach a catheter with a pharmaceutically active composition being located on the outer surface of the catheter. Hunter is therefore offered by the Examiner for teaching a catheter having pharmaceutically active composition (antimicrobial) on the outer surface of the catheter. As such, the Examiner alleges that it would have been obvious to one of ordinary skill in the art to provide the pharmaceutically active composition on the outer surface of the catheter of Nilsson, because Hunter teaches the predictable result of a pharmaceutically active composition being delivered to the user, when said composition is on the outer surface of the catheter. Applicant respectfully traverses this rejection.

Applicant submits that, as stated above with regard to the rejection under §102, Nilsson does not teach an intermittent catheter as understood by those of ordinary skill in the catheter arts. Moreover, neither Nilsson or Hunter, teach or suggest a catheter having a hydrophilic polymer coating, and at least a portion of the polymer coating being impregnated with a pharmaceutically active composition, where the composition is at least one agent selected from the group consisting of hormones,

efferent blocking agents, afferent blocking agents and sympathomimetic agents, and wherein said pharmaceutically active composition is coated with a water soluble coating.

Hunter is offered by the Examiner for teaching that a pharmaceutically active composition can be located on the outer surface of a urinary catheter. As Applicant has stated previously, Hunter actually teaches a catheter having an external surface coated with a mixture of hydrophilic polymer (lubricant) and an antimicrobial compound, along with other anti-inflammatory agents, soaps, or anti-oxidants to prevent urinary tract infection. Hunter does not teach any of the pharmaceutical compositions as claimed by Applicants. This is because Hunter is not directed to pharmacological treatment of urinary incontinence or overactive bladder contraction. Hunter is directed to reducing the risk of urinary tract infection and inflammation due to catheterization. There is no teaching or suggestion in Hunter, for treating incontinence in a patient, by delivering the compositions disclosed by Applicant, such as estrogens or substances that block parasympathetic nervous activity and related nerves, by applying said composition onto the outer surface of an intermittent catheter such that the composition is delivered to the urinary tract of a

patient during catheterization.

Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with regard to the rejected claims, because the combination of Nilsson in view of Hunter, does not teach each and every element of Applicant's claimed invention. Furthermore, the combination of Nilsson in view of Hunter does not provide any motivation to make an intermittent catheter for use in incontinent patients having a pharmaceutically active composition at least partially impregnated in a hydrophilic polymer coating, comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, wherein said catheter is adapted to deliver the composition in the lower urinary tract system during catheterization.

As stated in Applicant's previous amendment, with regard to rationales 3 and 4 in the KSR guidelines, Applicant points out that the Examiner has not provided any evidence that prior to Applicant's claimed invention, there existed any known techniques for treating incontinence or hyperactive bladder using Applicant's claimed compositions via administration directly into the urethra. Moreover, while Hunter teaches prevention of urinary tract

infection via application of antimicrobial agents onto a catheter, antimicrobial prophylaxis with anti-infective drugs was well known.

With regard to rationale 5 of the KSR guidelines, Applicant submits that Applicant's claimed invention could not be considered by one of ordinary skill to have been obvious to try, because previously, all the pharmaceutical compositions claimed by Applicant for use in treating hyperactive bladder or incontinence, were administered systemically, intra-vaginally, or in the bladder itself. Finally, the remaining rationales 6 and 7 of the KSR guidelines do not apply, because there was no teaching suggestion or motivation in the prior art for one of ordinary skill to combine the cited references to arrive at Applicant's claimed features, other than those found in Applicant's own disclosure.

In view of the foregoing, Applicant submits that the combination of teachings of Nilsson, in view of Hunter, cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

Claims 15-17 were also rejected under 35 USC §103(a), as unpatentable over Nilsson, in view of Hunter, and further in view of Martan et al. (Ceska Gynekol, Jan. 1999). According to the



Examiner, the combination of Nilsson, in view of Hunter, teaches all aspects of these claims except the hormone being estriol or estrogen. Martan et al. teach the use of estrogen intra-vaginally for the treatment of incontinence in women. The Examiner states that it would have been obvious to one of ordinary skill to use estriol or estrogen as the hormone in the device of Nilsson. Applicant respectfully traverses this rejection.

As Applicant has stated above, the combination of the teachings of Nilsson, in view of Hunter, fails to teach each and every element of Applicant's claimed invention, and does not provide any motivation to make Applicant's intermittent catheter having a pharmaceutically active composition where the composition is at least partially impregnated in a hydrophilic polymer coating, and wherein said catheter is adapted to deliver said pharmaceutically active composition in the lower urinary tract system during catheterization. This failure to teach all of Applicant's claimed features is not cured by the addition of Martan et al. As such, Applicant submits that the combination of teachings of Nilsson, in view of Hunter, and Martan et al. cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

Finally, the rejection of claims 18-20 under 35 USC §103(a) as unpatentable over Nilsson, in view of Hunter, and further in view of USP 6,039,967 to Ottoboni et al was also maintained. According to the Examiner, the combination of Nilsson in view of Hunter teaches all aspects of these claims except the use of oxybutynin. Ottoboni et al. is offered for teaching the treatment of incontinence by delivering to the urinary tract, a catheter coated with the composition. The Examiner states that it would have been obvious to one of ordinary skill to use oxybutynin as the pharmaceutically active composition as taught in Ottoboni et al. in the device of Nilsson. Applicant respectfully traverses this rejection.

As Applicant has stated previously, the combination of the teachings of Nilsson in view of Hunter, fails to teach each and every element of Applicant's claimed invention, and does not provide any motivation to make an intermittent catheter for use in incontinent patients having a pharmaceutically active composition, at least partially impregnated in a hydrophilic polymer coating, and comprising at least one agent selected from the group consisting of hormones, efferent blocking agents, afferent blocking agents and sympathomimetic agents, and said catheter being adapted

to deliver said pharmaceutically active composition in the lower urinary tract during catheterization. This failure to teach all of Applicant's claimed features is not cured by the addition of Ottoboni et al.

Ottoboni et al. do not teach treatment of incontinence by delivering oxybutinin to the lower urinary tract by the urethra. Rather, Ottoboni et al. teaches the placement of a sustained release formulation of a composition directly into the bladder, where the composition can be released. There is no teaching or suggestion of intra-urethral delivery of compositions via a catheter. As such, Applicant submits that the combination of teachings of Nilsson in view of Hunter and Ottoboni et al. cannot render Applicant's claimed invention *prima facie* obvious, and respectfully requests withdrawal of this rejection.

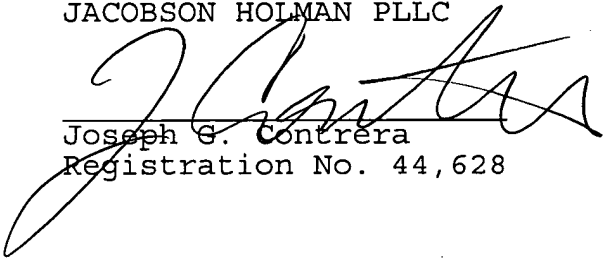
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. As such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to

USSN 10/538,832  
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telephone the undersigned at the number provided.

Respectfully submitted,

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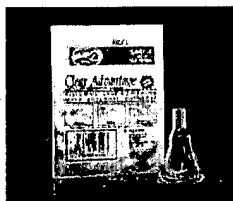


## Male External Catheters (MEC) vs. Internal Catheters

There are three main types of catheters; two are internal- intermittent and indwelling- and a third, external. So, is one better than the other? Here, we will discuss the differences between the three and the side effects that one should know before using.

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External catheter systems, also commonly referred to as condom cath, or Texas Catheter, are available for men. And while MEC's have been Stadium Pal & historically geared toward men, there are versions available for females as Galwell. These are designed with form-fitting cups.

These MEC's are dubbed safer to use than internal catheters because a Customer Care tube does not need to be placed in the bladder to remove urine. It allows the person to self cath. The catheter fits over the penis and connects to a drainage bag that is strapped to your leg. There are several different sizes and versions of MEC available. Many of this type are disposable and generally are reliable for about a day or two, which serves the purpose if the need is temporary. However, there are reusable external catheters for active men with incontinence, and are often used as an alternative to diapers and pads.

Although much safer than inserting a tube into the urethra, there are some problems associated with MEC's:

- Chance of infection, although far less than with internal
- Skin irritation and rashes could possibly occur from the friction caused by putting an external catheter in place. We offer [Shield Skins](#), and [Adhesive Removers](#) to help manage these problems.
- Catheter coming undone. For instance, in older men the penis may have retracted it may be difficult to keep it from staying on. This is where a [Retracted Penis Pouch](#) is an option.

For more information of the Types of Catheters at BioRelief.com [click here](#).

## Indwelling catheters

**Indwelling catheters** are a closed system inserted into the urethra to allow the bladder to drain, or in cases with a two-way catheter (Foley), fill up. Having two purposes is one reason that makes them different than external catheters, which only help empty. But because these devices are inserted into the urethra and bladder and left there over several weeks before being changed, problems can arise.

- First of all, when the device is initially inserted into the urethra, it can for some be painful and uncomfortable. Along with that can come a burning sensation and sometimes even spasms.
- Second, although a water-filled balloon inside the bladder usually

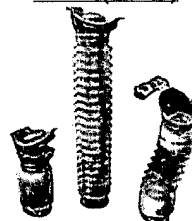
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tightly secures the catheter, sometimes the catheter can fall out. This could be a result of using the wrong size catheter.

- With this a third problem can arise- leakage or bypass, which means that urine comes out, but not through the tube.
- Blockage can also occur by using an internal cath as well. Bacteria, mucus or crystallization of protein can cause this.
- Finally, a urinary tract infection can occur from bacteria, leakage or blockage. In fact, UTI is the most common contracted hospital infection.
- Other infections could occur as well as a result of internals over several months.
- More serious results that could come about are bladder stones, blood in the urine, tearing of the urethra.

However, despite the problems that can occur with indwelling catheters, sometimes they are the only option. For example, pregnant women having an ultrasound done need full bladders to achieve a proper picture. If the bladder is not as full as it needs to be they will need to be catheterized with a Foley to fill the bladder with saline. Another, probably more prevalent, reason is that people who cannot manage using an intermittent cath themselves, which will be discussed in the next section, may find it easier to manage their everyday lives with an indwelling catheter. This is usually found in nursing homes, hospitals or with people with medical conditions who live alone in their own homes.

## Intermittent catheters

**Intermittent catheters** are another type of internal cath, although they are inserted and removed only when needed. This very sterile method of removing urine are used by people every three to four hours to void the body of residual urine that may still be in the bladder. Once the process is complete, the catheter is removed until the next time for use rolls around. Because the catheter is removed after each use, there is less chance of infection. Since it is easy to learn how to do so, this type of catheter is usually inserted by the user himself or by a family member, as opposed to the more permanent indwelling version in which a medical professional usually inserts it- and it stays.

There are not many side effects to using an intermittent catheter, however, there are some:

- There can be some swelling and tenderness around the urethra due to the reinsertion throughout the course of the days.
- Infection can also occur if sterilization techniques are not in place.

## Medical Uses

There are chronic medical conditions that may require someone to use internal or external catheters at all times, such as paralysis and bladder problems. However, sometimes someone otherwise totally healthy may also need to use them temporarily to help get them through the recovery process.

Incapacitating accidents, surgeries, illnesses and certain medical occurrences like a stroke can make going to the bathroom a chore on one's own. But thanks to biotechnology, it doesn't have to be. MEC's can aid in making the days and nights of the recovery process go much smoother.

Here are some examples of when and where our external catheters can come in handy:

### Hip Replacement/Pelvic Surgery

Many times it can be difficult

Prostate Surgery

### **Limited Mobility from Various Conditions/Injuries**

There are many surgeries that may require someone to use a wheelchair or be on complete on bed rest. Car accidents can result in leg, back and neck injuries. Falls, slips and other accidents can result in the same. When someone is confined temporarily to a bed and/or wheelchair, especially because they are not yet adjusted to their situation, getting up and around to use the bathroom when the urge to pee comes on may be difficult or even impossible. An MEC can be comfortably worn to help these patients stay dry during the recovery process.

### **More chronic-type illnesses that external catheters can aid:**

- Muscular Dystrophy
- Multiple Sclerosis
- Diabetes

### **Conclusion**

As you may have concluded yourself, the less a catheter is inside of you the safer it is. And, when it is not even in you, all the more better. MEC's present a clean, comfortable and easy-to-use option for those needing help emptying their bladders. Available in discreet versions for both men and women, many are beginning to see the benefits of this type of catheter. However, when health and medical reasons require it, there are more permanent versions as well.

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## Urinary Catheterization

### Definition

Urinary catheterization is the insertion of a catheter into a patient's bladder. The catheter is used as a conduit to drain urine from the bladder into an attached bag or container.

### Purpose

Urinary catheterization is employed in hospital and nursing home settings to maintain urine output in patients who are undergoing surgery, or who are confined to the bed and physically unable to use a bedpan. Critically ill patients who require strict monitoring of urinary output are also frequently catheterized.

Intermittent insertion of a urinary catheter is a treatment option for patients with certain types of [urinary incontinence](#). Patients who are unable to completely empty the bladder during urination (urinary retention), or patients who have a bladder obstruction, may also require intermittent urinary catheterization. Disabled individuals with neurological disorders that cause [paralysis](#) or a loss of sensation in the perineal area may also use regular intermittent catheter insertion to void their bladders.

### Precautions

Because urinary catheterization carries a risk of causing urinary tract infection (UTI), precautions should be used to keep the catheter clean and free of bacteria. Patients requiring intermittent catheterization should be well trained in the technique by a qualified health care professional.

### Description

Intermittent catheterization is performed a minimum of four times a day by the patient or a care giver. The genital area near the urethral opening is wiped with an antiseptic agent, such as iodine. A lubricant may be used to facilitate the entry of the catheter into the urethra, and a topical local anesthetic may be applied to numb the urethral opening during the procedure. One end of the catheter is placed in a container, and the other end is inserted into and guided up the urethra until urine flow begins. When urine flow stops, the catheter may be moved or rotated, or the patient may change positions to ensure that all urine has emptied from the bladder. The catheter is then withdrawn, cleaned, and sterilized for the next use. Recommended cleaning practices vary, from the use of soap and water to submersion in boiling water or a disinfectant solution. Some patients prefer to use a new catheter with each insertion.

Nonintermittent catheterization, which is initiated in a hospital or nursing home setting, uses the same basic technique for insertion of the urinary tract catheter. The catheter is inserted by a nurse or other health care professional, and remains in the patient until bladder function can be maintained independently. When the catheter is removed, patients will experience a pulling sensation and may feel some minor discomfort. If the catheter is required for an extended period of time, a long-term, indwelling catheter, such as a Foley catheter, is used. To prevent infection, it should be regularly exchanged for a new catheter every three to six weeks.

Use of indwelling catheters should be restricted to patients whose incontinence is caused by urinary tract obstruction that can not be treated, and for which alternative therapy is not feasible.

### Preparation

If a patient wishes to perform intermittent catheterization himself, training in the technique by a qualified health care professional is required. Basic instruction in the anatomy, antiseptic techniques, catheter insertion, and proper catheter care should be provided. Patients learning chronic intermittent urinary catheterization may also benefit from an ultrasound examination to verify that they are completely emptying their bladder during the procedure.

### Aftercare

Patients using intermittent catheterization as a treatment for incontinence will experience a

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period of adjustment as they try to establish a catheterization schedule that is adequate for their normal level of fluid intake.

Antibiotics may be prescribed as a preventative measure in long-term urinary catheterization patients who are at risk for urinary tract infection.

A patient with an indwelling catheter must be reassessed periodically to determine whether alternative treatment may be more effective in treating the problem.

## Risks

Trauma to the urethra and/or bladder may result from incorrect insertion of the catheter. Repeated irritation to the urethra during catheter insertion may cause scarring and/or stricture, or narrowing, of the urethra. The catheter may introduce bacteria into the urethra and bladder, resulting in urinary tract infection. UTI can cause fever and inflammation of the bladder and urethra. Patients who practice intermittent catheterization can reduce their risks for UTI by using antiseptic techniques for insertion and catheter care.

## Normal results

When used correctly, catheterization facilitates complete voiding of the bladder.

## Resources

### Periodicals

Hunt, Gillian M., Pippa Oakeshott, and Robert Whitaker. "Intermittent Catheterization: Simple, Safe, and Effective but Underused." *British Medical Journal* 312, no. 7023 (Jan. 1996): 103-7.

## Key terms

**Bladder obstruction** — A blockage of the bladder caused by the presence of calculi (e.g., mineral deposits) or an anatomic abnormality.

**Catheter** — A long, thin, flexible tube.

**Foley catheter** — A two-channel catheter with a balloon on the bladder end of one channel. Once inflated, the balloon keeps the catheter securely in the bladder. The other channel of the catheter facilitates the flow of urine out of the bladder.

**Local anesthetic** — Medication applied topically to the skin or administered through an injection that deadens a specific part of the body and inhibits the sensation of pain.

**Perineal area** — The genital area between the vulva and anus in a woman, and between the scrotum and anus in a man.

**Ultrasound examination** — A diagnostic test that uses sound waves to generate a picture of an organ or organ system.

**Urinary incontinence** — The inability to control one's urine flow.

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